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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,249	03/30/2004	Anna Depicker	2676-6388US	4486
24247	7590	01/10/2007		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER MEHTA, ASHWIN D	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/813,249

Applicant(s)

DEPICKER ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3302004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-12, and the species of plant hosts, in the reply filed on October 30, 2006 is acknowledged. The traversal is on the ground(s) that searches for Groups I and II should be co-extensive, because claim 13 is a product-by-process of claim 1 (response, page 1). However, the restriction requirement acknowledged that Group II and I are related as product and process of making. The restriction requirement also properly explained that the inventions are distinct because the product of Group II can be made by another process. Applicants also argue that no undue search burden should be presented to the Office, since a prior art search of Group II has already been conducted by the PCT authorities in the parent application, which search results were presented to the Office (response, page 2, 1st full paragraph). However, while the Office considers references cited by Applicants for patent in information disclosure statements, it still conducts its own prior art search. It is considered an undue burden to search the inventions of both groups together, as the invention of Group II can be produced by an alternative process. With regard to the species election, Applicants argue that all of the provisionally elected claims 1-12 are considered allowable, in view of the IPER issuing from the parent of this application (response, page 2). However, patentability determinations of foreign patent offices are irrelevant to patentability determinations of the USPTO. Applicants also argue that "two" seems to be a quintessentially reasonable number, and no unreasonable effort should be required to examine the claims (response, page 2). However, while the restriction requirement presented only two species, these two species are quite obviously

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different: plants versus all other non-plant organisms.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

Applicant has not filed certified copies of PCT/EP02/11188 and EPO 01203760.2.

Specification

3. The listing of references in the specification on page 13 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

4. On page 7, line 6 of paragraph [0027] indicates that Figure 3 presents locus X2. However, locus X2 is diagrammed in Figure 4. Correction is required.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "efficient" in line 1 renders the claim indefinite. The recitation is a relative term that has no definite meaning. What is efficient to one may not be so to another.

Further in claim 1: the recitation, "the recombinant gene comprises a region homologous with the silenced locus" renders the claim indefinite. The claim does not clearly indicate what this region in the recombinant gene is. As written, any sequence within the recombinant gene can have some level of homology with the silenced locus. The metes and bounds of the claim are unclear. Similarly, the recitation, "the target gene has homology with the recombinant gene" also renders the claim indefinite. Any gene can be said to have some sort of homology with the recombinant gene.

Furthermore in claim 1: the claim is missing an essential element. The claim indicates that the target gene has homology with the recombinant gene. However, the claim only indicates that the recombinant gene comprises a region homologous with the silenced locus, and the claim also indicates that the target gene is not to have significant homology with the silenced locus. The claim does not indicate that the recombinant gene comprises a region identical to a region of the target gene. See MPEP 2172.01.

In claims 3-6: the recitation, "of the hosts" renders the claims indefinite. The recitation implies that the method involves introducing the recombinant gene into more than one host.

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However, parent claim 1, in line 2, recites, "introducing a recombinant gene into *a* host" (emphasis added), which indicates the method involves only one host.

In claims 11-12: the recitation, "to obtain high throughput gene silencing" renders the claim indefinite. It is not exactly clear what is meant by this recitation. Paragraph [0013] of the specification discusses high throughput gene silencing. However, none of these steps recited in that discussion are in the claims, and limitations of the specification cannot be read into the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards a method for obtaining efficient RNA silencing of a target gene comprising: introducing a recombinant gene into a host (plants are the elected species) comprising a silenced locus and the target gene, wherein the recombinant gene comprises a region homologous with the silenced locus and the target gene has homology with the recombinant gene, but no significant homology with the silenced locus, thus RNA silencing the target gene.

The specification describes a method of causing RNA silencing of a target gene in a host

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plant. The method requires as starting material a host plant which comprises a locus that is already RNA silenced, which does not have significant homology with the coding sequence of the target gene. "No significant homology" is defined on page 4 as either overall homology of less than 40%, or that no contiguous sequence of at least 23 nucleotides are present. The method is discussed on pages 7-8 of the specification. Transgenic tobacco plants were evaluated for reduction in expression of the tobacco endogenous catalase (cat1) gene, in plants carrying a silencing locus (X locus) showing no significant homology with the catalase endogene, by introducing a recombinant gene (Y construct). As silencing locus, either construct X1 or X2 was used (FIG. 2: locus X1, containing the nptII coding sequence; FIG. 4: locus X2, containing the gus coding sequence). In either case, the silencing locus contained the 3' chalcone synthase gene sequences of *Anthirrinum majus* (3'chs), operably linked to the nptII or gus coding sequence. The host plant was therefore silenced for nptII or gus, as a result of RNA silencing triggered by transcription of X1 or X2, respectively. As transmitter for silencing of the target gene, a recombinant gene was constructed, which was composed of the catalase coding sequence, operably linked to the 3' chs region, and the CaMV 35S promoter (P35S) (residing on T-DNA pPs35SCAT1S3chs, Figs. 2 and 3, Y2). The recombinant cat1 3'chs genes (Y2) were introduced in tobacco leaves bearing locus X1 or X2 via *Agrobacterium* injection. As a negative control, a recombinant gene was used in which the cat1 coding sequence was replaced with the gus coding sequence (pGUSchsS, T-DNA construct as in locus Y1, FIG. 1). In this case, no stepwise homology was created between the silencing inducing locus and the target catalase endogenes. As a positive control, the recombinant construct Y2 was also introduced in transgenic tobacco with silenced catalase genes by the presence of a catalase antisense construct. Sixteen days

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after *Agrobacterium* injection, the catalase activity was determined in protein extracts of injected leaf tissue and compared with the activity in non-injected wild type leaf tissue (Table 2).

Catalase activity was reduced in 6 out of 7 samples, while it remained high in the negative controls.

However, the method as recited in claim 1 omits essential elements of the method as taught in the specification. The specification teaches that the recombinant gene comprises a 5' or 3' untranslated region, that is also operably linked to the coding sequence of the target gene in construct Y, and is found within construct X (page 7). While claim 1 indicates that the target gene has homology with the recombinant gene, the claim only indicates that the recombinant gene comprises a region homologous with the silenced locus. The claim does not recite that the recombinant gene also comprises a region of the coding sequence of the target gene, operably linked to a 5' or 3' untranslated region that is also operably linked to the coding sequence in construct X, which induces silencing of the initially silenced locus in the host plant. See MPEP 2164.08(c) and 2172.01. Similarly, claims 11 and 12 attempt to limit the method of parent claims 1 and 2 by reciting, "to obtain high throughput gene silencing". However, there is no mention of steps essential for this in the claims, which include the formation of a recombinant gene library, as discussed in paragraph [0013] of the specification.

Further, line 2 of claim 1 indicates that the host comprises a silenced locus. The specification indicates that the locus is RNA-silenced. However, this limitation cannot be read into the claim. As written, the claim broadly encompasses this locus being transcriptionally, as opposed to post-transcriptionally, silenced. In the absence of further guidance, undue experimentation would be required to practice the method when the initially silenced locus is

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transcriptionally silenced, as the method operates by exploiting the post-transcriptional silencing pathway of the host plant. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

7. Claims 1-12 are rejected and non-elected claim 13 is withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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